



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
CITY VIEW PLAZA II BUILDING, 7TH FLOOR
ROUTE 165 GUAYNABO, PUERTO RICO 00968

April 7, 2022

ELECTRONIC MAIL

Jorge A. Vivoni Farage
CEO
Steri-Tech, Inc.
Road 701 Km. 0.7
P.O. Box 1145
Salinas, Puerto Rico 00751

Re: NAO Thermal Oxidizer Stack Test Report - RFI # CAA-02-2019-1458

Dear Mr. Vivoni:

The United States Environmental Protection Agency ("EPA") has reviewed the NAO Thermal Oxidizer ("TO") Stack Test Report ("Report") prepared by LCH Consulting Associates, dated October 6, 2021, and submitted by Steri-Tech Inc. ("STI") via email on October 12, 2021. The Report contains the results and data from the TO stack test conducted on August 11 - 12, 2021. On October 13, 2021, EPA requested that STI provide additional information and identified several deficiencies that prompted several email communications and Report Addendums. A revised version of the Report was submitted on October 14, 2021. Subsequently, Report Addendum 1 and 2 were submitted on October 26, 2021, and November 15, 2021, respectively. As discussed with STI's counsel by phone on March 14, 2022, after reviewing the Report, Addendums, and information provided by STI, EPA has determined that the Report is substantively deficient and will not be approved. The following identifies the deficiencies found in the Report:

1. The test data in the Report is not adequately supported and documented in accordance with 40 C.F.R. § 63.7. EPA requested additional test data, which STI submitted in Addendums 1 and 2. However, the additional data and chromatograms were not incorporated and integrated into the Report and could not be evaluated linearly.
2. The data shows a series of periods in which the new calibration range of 502 ppm was exceeded (i.e., chromatograph files Steri-Tech NAO2021_678 (615 ppm); Steri-Tech NAO2021_984 (1,378 ppm); Steri-Tech NAO2021_985 (1,191 ppm); Steri-Tech NAO2021_1178 (1,760 ppm); and Steri-Tech NAO2021_1179 (2,000 ppm)). Such conditions where the calibration range of 502 ppm was exceeded are not described or identified in the Report. In addition, some of these values (i.e., Steri-Tech NAO2021_1178 (1,760 ppm) and Steri-Tech NAO2021_1179 (2,000 ppm)) were not correctly used during the averaging conducted to obtain the outlet EtO concentration, see Enclosure 1 for further details.

3. The data for the sterilization chamber vent runs, and the averaging conducted to obtain the outlet EtO concentration, include periods in which no purging occurred. Therefore, the calculation of the average and the EtO concentration is weighted/biased low. This condition can be seen both before and after the completion of each of the runs.
4. The data shows inconsistencies with the range of the chromatographs and there are instances where low ethylene oxide (“EtO”) concentration measurements are viewed at a very high range which makes the review and validation of the data impossible.
5. The performance test data provided was deficient and was not subject to adequate quality assurance and quality control procedures.

40 C.F.R. § 63.7(g)(2)(v) requires that “where a test method, CEMS, PEMS, or COMS performance specification, or on-going quality assurance requirement for a CEMS, PEMS, or COMS requires you record or report, the following shall be included in your report: Record of preparation of standards, record of calibrations, raw data sheets for field sampling, raw data sheets for field and laboratory analyses, chain-of-custody documentation, and example calculations for reported results.”

Also, in accordance with EPA’s national stack testing guidance,¹ “[t]he test report should include chain-of-custody information from sample collection through laboratory analysis including transport. It also should include sufficient raw data and cross correlations in the appendices such that a new set of calculations, including statistics could be independently generated from the raw data if necessary (e.g., median versus geometric-mean)” (emphasis added).

6. STI deviated from the test methods established in the approved test protocol and the performance test was not conducted under representative operating conditions, see 40 C.F.R. § 63.7(e)(1). During EPA’s November 10, 2021, meeting with the STI, Mr. Andres Vivoni indicated that the company did not complete any sterilization cycles for 3 days prior to the performance test. Therefore, because STI did not have recently sterilized product available for conducting the aeration rooms portion of the performance test, the test results do not adequately represent actual EtO emissions during normal, routine sterilization processes at the facility.
7. The tables containing raw gas chromatography flame-ionization detection (GCFID) data provided in Addendum 1 and the chromatograph sheets provided on Addendum 2 do not match. See Enclosure 1 for several examples showing these inconsistencies related to the calibration ranges reported.

For the foregoing reasons, EPA disapproves the Report. EPA acknowledges that STI has submitted a construction permit application to DNER for the construction and operation of a new catalytic oxidizer control device to control EtO emissions at the facility, for purposes of compliance with the applicable requirements in 40 C.F.R. Part 63, Subpart O. EPA further understands that STI agreed to remove the TO control device from the permit application as a potential backup control device. In light of EPA’s disapproval of the Report, STI must take all actions and submit any additional information that is necessary for issuance of the final construction permit by DNER for the catalytic oxidizer controls. EPA understands that once the catalytic oxidizer is permitted and in operation, STI will permanently cease operation of the TO as an EtO control device at the facility.

¹ https://www.epa.gov/sites/default/files/2013-09/documents/stacktesting_1.pdf

You may convey any questions concerning this matter to Alex Rivera of the Caribbean Environmental Protection Division, Multimedia Permits and Compliance Branch at 787-977-5845 or rivera.alex@epa.gov.

Sincerely,

Nancy Rodríguez, Chief
Multimedia Permits and Compliance Branch
Caribbean Environmental Protection Division

cc: Amarilys Rosario, Chief Air Quality Area, Department of Environmental and Natural Resources